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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,172	09/01/2005	Carlos del Pozo Losada	13566.105013	6504
65989	7590	12/13/2007		
KING & SPALDING 1185 AVENUE OF THE AMERICAS NEW YORK, NY 10036-4003			EXAMINER SOLOLA, TAOFIQ A	
			ART UNIT	PAPER NUMBER
			1625	
			NOTIFICATION DATE	DELIVERY MODE
			12/13/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptomailnyc@kslaw.com

Office Action Summary

Application No.

10/523,172

Applicant(s)

LOSADA ET AL.

Examiner

Taofiq A. Solola

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 13 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 23-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 2.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Claims 1-34 are pending in this application.

Claims 35-39 are canceled.

Claims 23-34 are drawn to non-elected invention.

Response to Restriction

The election of group I, claims 1-22, with traversal, in Paper filed 11/13/07, is hereby acknowledged. The traversal is on the basis that the ketone and the hemiketal isomers co-exist in equilibrium and therefore would not be a burden on the Examiner to search both. This is not persuasive because, existence of compounds in equilibrium is not a basis of restriction requirement under the US patent practice. The ketone and hemiketal have different structures and belong to different classes and subclasses. The Examiner is required to search each structure, class and each subclass, and would be undue burden to search both the ketone and hemiketal.

The restriction is still deemed proper and therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 7-8, 10-12, 15-18, 21-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims lack adequate support in the specification. The wobble lines in the compounds imply it is not stereo-specific. There is no support for such in the specification. The invention is directed to making both isomers at position 6 only. See schemes 1 and 2, pages 17 and 21, respectively. Also, claim 1 refers to a US patent. A claim must stand alone to define the invention, and incorporation into the claims by reference to the specification or an external source is not permitted. Ex parte Fressola, 27 USPQ 2d 1608, BdPatApp & Inter. (1993). In patent examination, it is essential for claims to be precise, clear, correct, and unambiguous. *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989). By deleting the claims the rejection would be overcome.

Claims 1-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for using the instant compounds as claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

"In the context of determining whether sufficient 'utility as a drug, medicament, and the like in human therapy' has been alleged, it is proper for the examiner to ask for substantiating evidence unless one with ordinary skill in the art would accept the [compounds and the utilities] as obviously correct." *In re Jolles*, 628 F.2d 1327, 1332 (Fed. Cir. 1980), citing *In re Novak*, 306 F.2d 924 (CCPA 1962); see 340 F.2d 974, 977-78 (CCPA 1965). "A specification disclosure which contains a teaching of the manner and process of making and using the invention . . . must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support." *In re Brana*, 51 F.3d 1560 (Fed. Cir. 1995), *Id.* at 1566, quoting *Marzocchi*, 439 F.2d 220, 223 (CCPA 1971); *Fiers v. Revel*, 984 F.2d 1164, 1171-72

(Fed. Cir. 1993), quoting *Marzocchi*, 439 F.2d at 223; see also *Armbruster*, 512 F.2d 676, 677 (CCPA 1975); *Knowlton*, 500 F.2d 566, 571 (CCPA 1974); *Bowen*, 492 F.2d 859 (CCPA 1974); *Hawkins*, 486 F.2d 569, 576 (CCPA 1973). Where there is "no indication that one skilled in the art would accept without question [the instant compounds and method of use] and no evidence has been presented to demonstrate that the claimed products do have those effects *Novak*, 306 F.2d at 928, an applicant has failed to sufficiently demonstrate sufficient utility and therefore cannot establish enablement." *In re Rasmusson*, 75 USPQ2d 1297 (CAFC 2005). The claimed utilities are not enabled for the following reasons:

For rejection under 35 U.S.C. 112, first paragraph, the following factors must be considered. *In re Wands*, 8 USPQ2d 1400, 1404 (CAFC, 1988):

"The factors to be considered [in making an enablement rejection] have been summarized as a) the breadth of the claims, b) the nature of the invention, c) the state of the prior art, d) the relative skill of those in that art, e) the predictability or unpredictability of the art, f) the amount of direction or guidance presented, g) the presence or absence of working examples, h) the quantity of experimentation necessary, *In re Rainer*, 146 USPQ 218 (1965); *In re Colianni*, 195 USPQ 150, *Ex parte Formal*, 230 USPQ 546.

The breathe of the claims encompass many compounds with different substituents. The compounds at positions R and R", have optionally substituted alkyl, alkenyl, alkynyl, as well as optionally substituted aryl, aminoalkyl, aralalkyl and optionally substituted heterocyclics. These are defined on pages 4-6 of the specification. The specification fails to provide conclusive evidence that schemes 1 and 2 are applicable to making the recited groups in pages 4-6. Given that the procedures are stereo-selective, steric interference is more than likely to be a problem in making the compounds as claimed, and the specification fails to disclose how one of ordinary skill would modify schemes 1-2 to overcome the problem. Even if made, there is no evidence in

the specification that such compounds would have the asserted utility. The compounds appear to be intermediates in schemes 1-2 instead of the product.

The racemate in claims 1-4, 7-8, 10-12, 15-18, 21-22, are not enabled. Schemes 1-2 are for making each isomer of position 6. The specification fails to set forth how the schemes could be modified to make racemate of position 6 much less all other positions. While it is possible to combine in equal proportions the isomers of position to make the racemate such is not supported in the specification. Even then, it is not deemed a synthetic process of position 6 racemate.

Hence, there is no absolute predictability or established correlation between different substituents at R and R" that they would behave in a certain way. The uncertainty presents one of ordinary skill in the art with obstacles and prevents her from accepting the instant invention on its face. It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved" and physiological activity is generally considered to be an unpredictable factor. See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Given the limited guidance in the specification one of ordinary skill in the art would have to perform significant amount of experiments to make and use the invention as claimed.

MPEP 2164.01(a) states, "[a] conclusion of lack of enablement means that, based on the evidence regarding any of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here. By deleting the claims the rejection would be overcome.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For reasons set forth above under 35 USC 112, first paragraph, the claims are indefinite.

Claim 10 is indefinite for failure to state what is claimed. The claim must recite the definition of R being claimed.

The requirement of 35 USC 112, is not what is obvious to one of ordinary skill in the art but a "full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same", *Lookwood v. American Airlines Inc.* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed Cir. 1997). By deleting the claims the rejection would be overcome.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Zheng et al., Chem. Pharm. Bull. (2000), Vol. 48(11), pp. 1761-1765.

Zheng et al., disclose compound 4(1) and composition thereof. The structure of the compound is racemate, which under the US patent practice comprises the isomers.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-22 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Zheng et al., Chem. Pharm. Bull. (2000), Vol. 48(11), pp. 1761-1765, Taylor et al., Tetrahed. Letts., (1998), Vol. 39, pp. 9361-9364, and Rinhehart et al., US 5,514,708, individually.

Applicant claims racemate, isomers of compounds of formula I, and composition thereof. In preferred embodiments the compounds are claimed with various known OH protecting groups.

Determination of the scope and content of the prior art (MPEP §2141.01)

Zheng et al., teach racemate of similar compound and its composition. See compound 4(1), page 1761. Taylor et al., and Rinhehart et al., teach position 6 racemate of similar compounds. See compound 4 of both prior arts.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant invention and that of the prior arts is that applicant claims both racemate and isomers instead of racemate by the prior arts. Also, applicant claims the compounds with known OH protecting groups.

Finding of prima facie obviousness--rational and motivation (MPEP §2142.2413)

However, racemate embraces the isomers. Isomer is not patentable over another isomer or racemate absent a showing of new and unexpected properties. *In re Brenner*, 147 USPQ 87

(DDC, 1965), 247 F.Supp 51, 56. Therefore, the instant invention is prima facie obvious from the teachings of the prior arts. One of ordinary skill in the art would have known to claim the racemate and/or isomer, and add known OH protecting groups at the time the instant invention was made. The motivation is from the expectation that the isomers and racemate would have similar biological activities, and from knowing that the protecting groups are useful for protecting OH group.

Alternatively, the instantly claimed compounds and OH protecting groups on are not applicant's invention. Applicant has done no more than combine separate but well-known inventions. While the combination may perform a useful function it did no more than what they would have done separately. *In re Anderson*, 396 U.S. 57, 163 USPQ 673 (1969) cited in *KSR Int. Co. v. Teleflex Inc*, 550 U.S. ----, 82 USPQ2d 1385 (2007). When a patent simply arranges old elements with each performing the same function it had been known to perform and yields predictable result, the combination is obvious. *In re Sakraida*, 425 US 273, 189 USPQ 449 (1976) cited in *KSR, supra*. A patent for such combination "obviously withdraws what is already known into the field of its monopoly." *Great Atlantic & Pacific Tea Co. v. Supermarket Equipment Corp.*, 340 U.S. 147, 187 USPQ 303 (1950), cited in *KSR, supra*.

Objection

Claims 3-6, 8-9, 18-20 are objected to for containing non-elected invention.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taofiq A. Solola, PhD. JD., whose telephone number is (571) 272-0709.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

A handwritten signature in black ink, appearing to read 'Taofiq Solola', with a stylized flourish at the end.

TAOFIQ SOLOLA
PRIMARY EXAMINER

Group 1625

December 5, 2007